IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, ASTRAZENECA AB, and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. HEC PHARM CO., LTD., HEC PHARM GROUP, and HEC PHARM USA, Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, AstraZeneca AB, and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiff"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants HEC Pharm Co., Ltd. ("HEC Co."), HEC Pharm Group ("HEC Group"), and HEC Pharm USA ("HEC USA") (collectively, "HEC" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208508 ("ticagrelor ANDA") filed by Defendant with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's BRILINTA® (ticagrelor) drug product prior to expiration of AstraZeneca's U.S. Patent Nos. 7,265,124 ("the '124 patent"), and 8,425,934 ("the '934 patent") that are listed in the *Approved Drug Products*

with Therapeutic Equivalence Evaluations ("Orange Book") for BRILINTA® (collectively "the Orange Book Patents").

PARTIES

2. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for cardiovascular diseases.

3. Plaintiff AstraZeneca LP, the holder of New Drug Application ("NDA") No. 022433 for BRILINTA® (ticagrelor), is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Plaintiff AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca AB is the owner of the '124 and '934 patents.

5. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP markets and sells BRILINTA® in this judicial district and throughout the United States, and Defendant specifically directed its Notice Letters into the State of Delaware to AstraZeneca Pharmaceuticals LP.

6. On information and belief, HEC Group is a corporation organized and existing under the laws of China, having a principal place of business at Dong Yang Guang Park, Shangsha, Chang'an, Dongguan, Guangdong, 523871, China.

7. On information and belief, HEC Group, itself and through its affiliates and subsidiaries, including HEC Co. and HEC USA, formulates, manufactures, packages, and

markets generic drug products for distribution in the District of Delaware and throughout the United States.

8. On information and belief, HEC Co. is a corporation organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China. On information and belief, HEC Co. is a wholly-owned subsidiary of HEC Group.

9. On information and belief, HEC USA is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 116 Village Blvd, Suite 200, Princeton, New Jersey 08540. On information and belief, HEC USA is a wholly-owned subsidiary of HEC Co. On information and belief, HEC USA is a U.S. agent of HEC Group and HEC Co.

10. On information and belief, HEC Co., itself and through its U.S. agent, Defendant HEC Pharm USA Inc., formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

JURISDICTION AND VENUE

11. Each of the preceding paragraphs 1 to 10 is re-alleged and re-incorporated as if fully set forth herein.

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. On information and belief, this Court has jurisdiction over HEC Group. On information and belief, HEC Group, directly or through its subsidiaries HEC Co. and HEC USA,

manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. On information and belief, HEC Group purposefully has conducted and continues to conduct business, directly or through its subsidiaries in the District of Delaware, and this judicial district is a likely destination of HEC Group's generic products.

15. On information and belief, this Court has jurisdiction over HEC Co. On information and belief, HEC Co., directly or through its subsidiary HEC USA, manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. On information and belief, HEC Co. purposefully has conducted and continues to conduct business, directly or through its subsidiary HEC USA in the District of Delaware, and this judicial district is a likely destination of HEC Co.'s generic products.

16. On information and belief, this Court has jurisdiction over HEC USA. On information and belief, directly or indirectly, HEC USA manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States.

17. Upon information and belief, HEC's website states that

> HEC Pharm Group was established in 2002. Today HEC Pharm includes 4 subsidiaries with manufacturing facilities. They are HEC Pharm Co. Ltd. and Yichang Changjiang Pharmaceutical Co., Ltd. both located in Hubei, China, Sunshine Lake Pharma Co., Ltd. and Ruyuan HEC pharm Co., Ltd. located in Guangdong, China…. We now have more than 213 domestic sales offices which include 1,500 medical representatives with that number expected to expand to 3,000 by 2017. At the same time our sales team operates overseas branches in the United Stated [sic], Germany, Japan and Australia.

http://www.hecpharm.com/about-hec/hec-group.html (accessed Nov. 4, 2015).

18. On information and belief, as set forth on HEC's website, HEC Group, HEC Co. and HEC USA hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

19. On information and belief, HEC Group, HEC Co. and HEC USA work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of Delaware and throughout the United States.

20. On information and belief, HEC Group, HEC Co. and HEC USA acted in concert to develop the proposed generic product that is the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA product in the District of Delaware and throughout the United States.

21. On information and belief, the preparation and submission of the ticagrelor ANDA by HEC Co. was done at the direction, under the control, in concert with, and/or for the direct benefit of HEC Group and HEC USA.

22. Further, on information and belief, HEC will manufacture, market, and/or sell within the United States the generic product described in the ticagrelor ANDA if FDA approval is granted. If the ticagrelor ANDA is approved, on information and belief the generic product would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

23. In *Novartis A.G. et al. v. HEC Pharm Co. Ltd., et al.*, C.A. No. 15-cv-00151, this Court denied without prejudice to renew HEC's motion to dismiss for lack of personal jurisdiction. *See id.* at D.I. No. 27 (Minute Entry for Oral Order entered May 11, 2015). The

Court later denied a Motion for Certification for Interlocutory Appeal on the issue. *Id.* at D.I. No. 46 (Minute Entry for Oral Order entered June 23, 2015). Furthermore, HEC availed itself of Delaware courts through the assertion of counterclaims in the same case. *See id.* at D.I. No. 32.

24. HEC is also subject to personal jurisdiction in this district because, *inter alia*, HEC has committed, aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff, including Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca LP, which are both Delaware limited partnerships. For example, HEC sent the Notice Letter into the State of Delaware to AstraZeneca Pharmaceuticals LP, which is incorporated in and has its principal place of business in Delaware, which has led and/or will lead to foreseeable harm and injury to the Plaintiff in Delaware.

25. HEC is also subject to personal jurisdiction in this district because as HEC itself argued during briefing of the *Novartis* motion to dismiss, "specific jurisdiction over Mylan existed in [*AstraZeneca AB v. Mylan Pharms., Inc.*, 2014 U.S. Dist. LEXIS 156660 (D. Del. Nov. 5, 2014)] because the notice letter was mailed ***into Delaware***….Therefore…where the notice letter was mailed is one of the primary factors to consider in determining the existence of specific jurisdiction." *Novartis A.G. et al. v. HEC Pharm Co. Ltd., et al.*, C.A. No. 15-cv-00151, D.I. No. 22 at PageID # 313 (HEC Pharm Co., Ltd. et al.'s Reply to Plaintiffs' Opposition to Defendants' Motion to Dismiss for Lack of Personal Jurisdiction filed March 27, 2015) (emphasis in original).

26. On the basis of HEC's own arguments before this Court, the Court has personal jurisdiction over HEC because HEC mailed the Notice Letter for its ticagrelor ANDA into Delaware to AstraZeneca Pharmaceuticals LP, a Delaware corporation.

27. This Court also has personal jurisdiction over HEC because, *inter alia*, HEC has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the state of Delaware. On information and belief, HEC regularly and continuously transacts business within the state of Delaware, including by selling pharmaceutical products in Delaware, directly and/or through affiliates, and/or by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware. On information and belief, HEC derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

28. For example, on information and belief, HEC Group has incorporated at least two subsidiary pharmaceutical entities in Delaware. On November 2, 2009, HEC Group incorporated an entity in Delaware named "HEC Pharm Inc." under file number 4748880. On information and belief, HEC Pharm Inc. had common employees with HEC Group and HEC USA. On information and belief, HEC Pharm Inc.'s Delaware corporate status was changed to inactive in 2012 when it failed to re-identify a Delaware agent for service.

29. In addition, on information and belief, HEC Group incorporated a company called Sunshine Lake LLC in Delaware on February 14, 2006, which remains in good standing and has indicated Valis Group Inc., 501 Silverside Rd. Suite 105, Wilmington, Delaware 19809 as its Delaware agent for service.

30. Moreover, on information and belief, HEC has entered into several distribution contracts with Delaware corporations to distribute drug products in the United States. For example, a press release by Delaware corporation Lannett Company, Inc. released on May 12, 2014 indicated that "[Lannett]…has entered into distribution and contract manufacturing services

agreements with Sunshine Lake LLC, the U.S. subsidiary of the HEC Pharm Group (HEC) of Shenzhen, Guangdong Province, China." According to this press release, "[u]nder terms of the distribution agreement, Lannett will be the exclusive distributor in the U.S. for Sunshine Lake's Zidovudine generic pharmaceutical product in finished dosage form." Moreover, "[t]he companies have also agreed to co-develop, over the next three years, 25 dosage formulations." http://www.businesswire.com/news/home/20140512005747/en/Lannett-Announces-Multi-Services-Agreement-Sunshine-Lake-LLC (accessed Nov. 5, 2015).

31. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over HEC.

PATENTS-IN-SUIT

32. On September 4, 2007, the U.S. Patent and Trademark Office duly and legally issued the '124 patent, entitled "Cristalline and amorphous form of a triazolo (4,5-D) pyridimine compound." A true and correct copy of the '124 patent is attached hereto as **Exhibit A**. The claims of the '124 patent are valid and enforceable. AstraZeneca AB is the owner of the '124 patent by assignment and has the right to enforce it.

33. On April 23, 2013, the U.S. Patent and Trademark Office duly and legally issued the '934 patent, entitled "Pharmaceutical compositions." A true and correct copy of the '934 patent is attached hereto as **Exhibit B**. The claims of the '934 patent are valid and enforceable. AstraZeneca AB is the owner of the '934 patent by assignment and has the right to enforce it.

34. AstraZeneca LP is the holder of NDA No. 022433 by which FDA granted approval for the marketing and sale of ticagrelor tablets in 90 mg and 60 mg dosage strengths, to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI). AstraZeneca markets

ticagrelor tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "BRILINTA®." FDA's official publication of approved drugs, the Orange Book, includes BRILINTA® in 90 mg and 60 mg dosage strengths together with the Orange Book Patents (including the '124 and '934 patents).

INFRINGEMENT BY DEFENDANT

35. Each of the preceding paragraphs 1 to 34 is re-alleged and re-incorporated as if fully set forth herein.

36. In a letter dated September 29, 2015 ("the Notice Letter"), HEC notified AstraZeneca LP that HEC Co. had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

37. The Notice Letter states that HEC is seeking approval from FDA to engage in the commercial manufacture, use, and sale of generic ticagrelor tablets before the expiration of the '124 and '934 patents. On information and belief, HEC intends to engage in the commercial manufacture, use, and sale of its generic ticagrelor tablets after receiving FDA approval to do so.

38. In the Notice Letter, HEC notified AstraZeneca that its ANDA contained a "Paragraph IV certification" asserting that the '124 and '934 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of HEC's generic ticagrelor tablets.

39. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '124 PATENT)

40. Each of the preceding paragraphs 1 to 39 is re-alleged and re-incorporated as if fully set forth herein.

41. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '124 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

42. On information and belief, upon FDA approval of Defendant's ticagrelor ANDA, Defendant will further infringe at least one claim of the '124 patent by making, using, offering to sell, and selling its generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

43. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '124 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '934 PATENT)

44. Each of the preceding paragraphs 1 to 43 is re-alleged and re-incorporated as if fully set forth herein.

45. Defendant's submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic ticagrelor tablets prior to the expiration of the '934 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

46. If Defendant's marketing and sale of generic ticagrelor tablets prior to expiration of the '934 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully prays that this Court grant the following relief:

A. A judgment that the claims of the '124 and '934 patents are not invalid, not unenforceable, and are infringed by Defendant's submission of its ticagrelor ANDA, and that Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets will infringe the '124 and '934 patents.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's ticagrelor ANDA shall be a date which is not earlier than the latest expiration date of the '124 and '934 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's generic ticagrelor tablets until after the latest expiration date of the '124 and '934 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

D. Damages or other monetary relief to AstraZeneca if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's generic ticagrelor tablets prior to the latest expiration date of the '124 and '934 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: November 12, 2015

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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